K131234

510(k) Summary

1. Date of Summary

October 10, 2013

2. 510(k) Applicant

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OCT 15 2013

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3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
Olympus Guide Sheath	Olympus Medical Systems Corporation	K060243, cleared to market on June 23, 2006

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working

channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope. The bronchoscope is advanced to a predefined target following guidance of the LungPoint Software (previously cleared under 510(k) #K112051 to guide endoscopic tools or catheters in the lungs or to enable marker placement in soft lung tissue).

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

The LungPoint Sheath has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

The LungPoint Dilation Balloon has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

6. Intended Use

The LungPoint Tools are endoscopic tools intended to be used with LungPoint Software guided bronchoscopes. The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue. The LungPoint Dilation Balloon is intended to dilate tissue of the bronchial tree and may be inserted through the LungPoint Sheath or directly through the working channel of the bronchoscope. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with a bronchoscope guided by the LungPoint Software are all within the intended use of the predicate devices, which is to aid in reaching a target in the respiratory organ

either directly as is the case with the sheath or through dilating target tissue with the dilation balloon. The technological characteristics of the subject devices are the same as those of the predicate devices with the following exceptions

- LungPoint Balloon: balloon size and length, balloon burst pressure and balloon catheter length as outlined.

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Balloon Size and Inflation (balloon pressure)	8mm @ 3 ATM 9mm @ 5.5 ATM 10mm @ 9 ATM	4mm @ 10 ATM
Catheter Length (cm)	155	143
Balloon Length (cm)	3.0	0.6
Rated Burst Pressure (atmospheres)	9	20

- LungPoint Sheath: stylet, catheter ID/OD and catheter length as outlined.

	Olympus Guide Sheath (K060243)	LungPoint Sheath
Stylet Provided	No	Yes - used to enhance pushability and to prevent airway mucosa entering sheath
Catheter ID/OD	2.1/2.7 mm	2.0/2.6 mm
Catheter Length	900 mm	975 mm

None of these differences raise new questions of safety and effectiveness. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Balloon deflation time
- Radiopacity.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. Specifically, cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity (acute) were tested. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

October 15, 2013

Broncus Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K131234
Trade/Device Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 26, 2013
Received: August 27, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131234

Device Name: LungPoint Tools - LungPoint Dilation Balloon and LungPoint Sheath

Indications for Use: The LungPoint Tools are endoscopic tools intended to be used with LungPoint Software guided bronchoscopes. The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue. The LungPoint Dilation Balloon is intended to dilate tissue of the bronchial tree and may be inserted through the LungPoint Sheath or directly through the working channel of the bronchoscope. Not for pediatric use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Srinivas Nandkumar -S